

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

FILED
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MAY 25 2016

U.S. DISTRICT COURT
DISTRICT OF MASS.

Case No. 16- civ- _____

COMPLAINT

JURY TRIAL DEMANDED

**FILED IN CAMERA AND
UNDER SEAL PURSUANT
TO 31 U.S.C. § 3730(B)(2)**

[DO NOT UPLOAD TO PACER]

UNITED STATES OF AMERICA, STATE OF
CALIFORNIA, STATE OF COLORADO,
STATE OF CONNECTICUT, STATE OF
DELAWARE, STATE OF FLORIDA, STATE OF
GEORGIA, STATE OF HAWAII, STATE OF
ILLINOIS, STATE OF INDIANA, STATE OF
IOWA, STATE OF LOUISIANA, STATE OF
MARYLAND, COMMONWEALTH OF
MASSACHUSETTS, STATE OF MICHIGAN,
STATE OF MINNESOTA, STATE OF
MONTANA, STATE OF NEVADA, STATE OF
NEW JERSEY, STATE OF NEW MEXICO,
STATE OF NEW YORK, STATE OF NORTH
CAROLINA, STATE OF OKLAHOMA, STATE
OF RHODE ISLAND, STATE OF TENNESSEE,
STATE OF TEXAS, STATE OF VERMONT,
COMMONWEALTH OF VIRGINIA, STATE OF
WASHINGTON, AND THE DISTRICT OF
COLUMBIA

ex rel. ROBERT E. MANCHESTER,

Plaintiffs,

v.

PURDUE PHARMA, L.P.
PURDUE PHARMA, INC.,
and THE PURDUE FREDERICK COMPANY,

Defendants.

X

Qui Tam Plaintiff Robert E. Manchester, as Relator, brings this action on behalf of the United States of America, pursuant to the federal False Claims Act, 31 U.S.C. § 3729 *et seq.* (“Federal FCA”), and on behalf of the Plaintiff States under their respective false claim acts (“State FCAs”) against Defendants Purdue Pharma, L.P., Purdue Pharma, Inc. and The Purdue

Frederick Company (collectively “Purdue” or the “Company”). Relator files this suit *in camera* and under seal, pursuant to 31 U.S.C. § 3730(B)(2) and alleges the following:

PRELIMINARY STATEMENT

Purdue’s original formulation of OxyContin, launched in early 1996, is well-known as a central force in the evolution of a national epidemic of opioid addiction. In 2001, Purdue abandoned the misrepresentations and fraudulent marketing practices that minimized and denied OxyContin’s potential for abuse and illicit diversion to persons at risk for opiate addiction, and eventually led the Company and two of its executives to plead guilty to criminal misbranding. Purdue’s conduct during the period from 1996 to 2001 perpetrated a fraud on health care providers and patients who relied on the Company’s false assurances. Beginning in 2001, amendments to OxyContin’s label included cautionary language regarding the drug’s abuse potential.

But those warnings were meaningless to the segment of the OxyContin market - - addicts and drug dealers - - who sought the drug specifically because it was so readily susceptible to abuse. From its debut until Purdue’s Reformulated OxyContin hit the market in August 2010, the pill’s matrix suffered from an inherently dangerous design defect: OxyContin tablets lacked the physical or chemical strength to avoid pulverization that rendered the pill’s controlled-release feature easily destroyed, releasing at once an entire dose of oxycodone that could be snorted, ingested, or injected to deliver a high that some abusers describe as rivaling heroin.

The illicit market for OxyContin thrived because after the revelations of 2001, Purdue continued to supply the drug to certain doctors, pharmacies, clinics and other health care services providers in quantities and under circumstances that would lead any reasonable pharmaceutical

company to conclude that the drug was being dispensed for illicit non-medical use and diversion. By so doing, Purdue caused and tacitly colluded with those reckless and felonious persons and entities to submit claims for government reimbursement that falsely certified that they were based upon medical necessity. Each of those false claims submitted to the Plaintiff Governments perpetrated a fraud on the government.

The opioid addiction epidemic is a catastrophe that is all the more acute because the design defect that made the OxyContin tablets as originally formulated readily susceptible to crushing and abuse was remediable. The technology to create a safer alternative to the original formulation of OxyContin was scientifically and economically feasible and practical, and disclosed and present within the general knowledge of pharmaceutical industry by 1997 if not before. It is now known and settled that the technology for an abuse-proof tablet was developed and disclosed a full thirteen years before Purdue received approval to market and sell a reformulated and abuse-resistant OxyContin tablet. Beginning in or around January 1, 1996 until August 2010, Purdue sold Original OxyContin with an inherently dangerous design defect that rendered the medication unsafe and unfit for its intended use, and for more than a decade, Purdue failed to incorporate known and disclosed technology to cure that defect.

The human suffering resulting from the rampant addiction attributable to Purdue's conduct is tragic and immeasurable. The consequential economic burden to state and federal governments, borne by taxpayers, amounts to billions of dollars paid (i) to reimburse fraudulent claims submitted to the plaintiff governments in the absence of medical necessity, (ii) to provide for the ongoing care and treatment of addicted Americans, and (iii) to reimburse claims for a product that was inherently dangerous, defective in design, and unfit for its intended use. This is an outcome that neither the law nor equity should tolerate.

JURISDICTION and VENUE

1. This is a civil action by Relator, acting on behalf of and in the name of the United States and the Plaintiff States, against the Defendants under the federal False Claims Act, 31 U.S.C. §§ 3729-3733, and analogous state false claims laws.

2. This Court has jurisdiction over the claims brought on behalf of the United States pursuant to 28 U.S.C. §§ 1331 and 1345, and 31 U.S.C. § 3732(a).

3. This Court has jurisdiction over the common law claims alleged herein under 31 U.S.C. § 3732(b). In addition, the Court has supplemental jurisdiction over the claims brought on behalf of the Plaintiff States under 28 U.S.C. § 1367.

4. Venue is appropriate in this district under 28 U.S.C. § 1391(b)-(c) and 31 U.S.C. § 3732(a) because Defendants can be found, reside, or have transacted business in this judicial district, and acts proscribed by 31 U.S.C. § 3729 have been committed in this district.

THE PARTIES

5. Plaintiff/Relator Robert E. Manchester is a resident of Vermont and an attorney. Mr. Manchester has provided the Plaintiff Governments on whose behalf he brings this action with a copy of this Complaint with substantially all material evidence and information possessed by Relator prior to filing, pursuant to 31 U.S.C. § 3730(b)(2).

6. The real parties in interest in this action are the governments of the United States of America and the Plaintiff States (together the “Plaintiff Governments”). On behalf of the Plaintiff Governments, Relator seeks damages resulting from the submission of false claims to government health insurance programs under the Federal FCA, 31 U.S.C. § 3729 *et seq.*, the Plaintiff States’ respective false claims acts identified in ¶ 11 *infra*, and under common law principles of product liability and unjust enrichment.

7. Plaintiff States have enacted false claims acts, which apply to each respective state's portion of Medicaid losses caused by submission of false claims to the Medicaid program funded jointly by the federal and state governments, or by conspiracy to do so. Relator seeks damages on behalf of the Plaintiff States, pursuant to the statutes set forth in paragraph 11, *infra*.

8. Defendants Purdue Pharma L.P. and Purdue Pharma Inc. are limited partnerships organized under the laws of Delaware with a principal place of business in Stamford, Connecticut. Defendant The Purdue Frederick Company, Inc. is a Delaware corporation with its principal place of business in Stamford, Connecticut.

9. Purdue is a manufacturer and seller of pharmaceutical products, including the pain medication OxyContin Controlled-Release Tablets, which as formulated originally was manufactured and sold during the period between approximately January 1, 1996 and August 10, 2010 ("Original OxyContin" or the "Drug") and thereafter in a reformulated version ("Reformulated OxyContin").

THE APPLICABLE STATUTES

10. Plaintiff United States of America administers the federal Medicare and Medicaid programs, among others. On behalf of the United States, Relator seeks damages resulting from the submission of false claims to federal health insurance programs under the Federal FCA, 31 U.S.C. § 3729 *et seq.*

11. Plaintiff States have enacted false claims acts, which apply to each respective state's portion of Medicaid losses caused by submission of, or conspiracy to submit, false claims to the Medicaid program, which is funded jointly by the federal and state governments. Relator seeks damages on behalf of the Plaintiff States, pursuant to the following statutes: the California False Claims Act (Cal. Gov. Code section 12650 *et seq.*); the Colorado Medicaid False Claims

Act (Colo. Rev. Stat. section 25.5-4-303.5 *et seq.*); the Connecticut False Claims Act (Conn. Gen. Stat. Ann. section 17b-301a *et seq.*) (amended and re-codified as Conn. Gen. Stat. Ann. section 4-274 *et seq.*); the Delaware False Claims and Reporting Act (Del. Code Ann. section 1201 *et seq.*); the Florida False Claims Act (Fla. Stat. Ann. section 68.081 *et seq.*); the Georgia State Medicaid False Claims Act (Ga. Code Ann. section 49-4-168), the Georgia Taxpayers Protection and False Claims Act (Ga. Code Ann. section 23 - 3 – 121 *et seq.*); the Hawaii False Claims Act (Haw. Rev. Stat. Ann. section 661-21 *et seq.*); the Illinois Whistleblower Reward and Protection Act (740 Ill. Comp. Stat. Ann. section 175/1 *et seq.*); the Indiana False Claims and Whistleblower Protection Act (Ind. Code Ann. section 5-11-5.5 *et seq.*); the Iowa False Claims Act (Iowa Code Ann. section 685.1 *et seq.*); the Louisiana Medical Assistance Programs Integrity Law (La. Stat. Ann. section 46:437.1 *et seq.*); the Maryland Health Program Integrity and Recovery Act (Md. Code Ann. Health- Gen. section 2-601 *et seq.*); the Massachusetts False Claims Law (Mass. Gen. Laws Ann. ch. 12 section 5A *et seq.*); the Michigan Medicaid False Claims Act (Mich. Comp. Laws Ann. section 400.601 *et seq.*); the Minnesota False Claims Act (Minn. Stat. Ann. section 15C.01 *et seq.*); the Montana False Claims Act (Mont. Code Ann. section 17-8-401 *et seq.*); the Nevada False Claims Act (Nev. Rev. Stat. Ann. section 357.010 *et seq.*); the New Jersey False Claims Act (N.J. Stat. Ann. section 2A:32C-1 *et seq.*); the New Mexico Medicaid False Claims Act (N.M. Stat. Ann. section 27-14-1 *et seq.*); the New York False Claims Act (N.Y. Fin. Law section 187 *et seq.*); the North Carolina State False Claims Act (N.C. Gen. Stat. Ann. section 1-605 *et seq.*); the Oklahoma Medicaid False Claims Act (Okla. Stat. Ann. tit. 63, section 5053 *et seq.*); the Rhode Island State False Claims Act (R.I. Gen. Laws Ann. section 9-1.1-1 *et seq.*); the Tennessee False Claims Act and Medicaid False Claims Act (Tenn. Code Ann. sections 4-18-101 *et seq.* and 71-5-181 *et seq.*); the Texas Medicaid False

Claims Fraud Prevention Law (Tex. Hum. Res. Code Ann. section 36.001 *et seq.*); the Vermont False Claims Act (32 V.S.A. section 630 *et seq.*); the Virginia Fraud Against Taxpayers Act (Va. Code Ann. section 8.01-216.1 *et seq.*); the Washington State Medicaid Fraud False Claims Act (Wash. Rev. Code Ann. section 74.66.005 *et seq.*; and the District of Columbia False Claims Act (D.C. Code Ann. section 2-381.01 *et seq.*). Each of the statutes listed above contain *qui tam* provisions authorizing a relator to bring an action on behalf of the State to recover damages and penalties pursuant to such statutes.

12. Federal law and regulations, applicable to participating states, obligate any health care practitioner and any other provider of health care services that may be reimbursed by Medicaid or Medicare to assure, to the extent of their authority, that services or items ordered or provided to beneficiaries and recipients will be (1) provided only when medically necessary, (2) of a quality that meets professionally recognized health care standards, and (3) supported by evidence of medical necessity and quality. 42 U.S.C. § 1320c-5, 42 C.F.R. § 1004.10. Plaintiff States' specific Medicaid programs provide similarly that payment will be made only for claims based on medical necessity, as defined therein.

FACTUAL BACKGROUND

Purdue launches its new product, OxyContin

13. In December 1994, Purdue submitted a new drug application under section 505(b) of the Federal Food, Drug, and Cosmetic Act ("NDA 20-533") for OxyContin (oxycodone hydrochloride) Controlled-Release Tablets, 10 mg, 20 mg, and 40 mg doses. Subsequent supplements to the NDA resulted in FDA approval for 80 mg and 160 mg tablets. ("Original OxyContin")

14. The product's active ingredient, oxycodone hydrochloride, is a Schedule II controlled substance that presents a risk of opiate addiction to its users similar to morphine. According to the FDA in its review of Original OxyContin, "Oxycodone is a semi synthetic opioid agonist that has been available for clinical use since 1917." Initially used to treat pain resulting from malignancy, oxycodone eventually was prescribed to manage chronic pain that was not cancer related.

15. Within months of submitting NDA 20-553 Purdue learned through market research conducted in early 1995 that its proposed product raised serious concerns among physicians regarding OxyContin's abuse potential.

16. Purdue sought to relieve such concerns with misleading representations regarding the product's addictive properties in its NDA submissions, which were approved, and its marketing.

17. Clinical studies submitted by Purdue in support of NDA 20-533 claimed that 12 hour doses of OxyContin were as safe and effective as 6 hour doses of immediate release oxycodone.

18. The OxyContin product insert that was approved by the FDA stated that the Drug was intended to be used "for the management of moderate to severe pain for patients for whom the use of opioid analgesic was indicated for more than several days."

19. From December 12, 1995 through June 30, 2001 Purdue made promotional claims that OxyContin "was less addictive, less subject to abuse or other diversion, or less likely to cause tolerance and withdrawal than other medication." But Purdue had not provided the FDA with clinical data demonstrating the basis for those claims in its NDA.

20. Internal Medical Officer Reviews (“MORs”) that the FDA, with Purdue’s participation, completed in or around October 1995 included statements that at a minimum cast doubt upon the veracity of Purdue’s claims. Those statements include:

- (i) “The blood level data in clinical use suggests that opioid effects [of OxyContin and immediate-release oxycodone] would be similar;”
- (ii) “The best conclusion is that the efficacy of [OxyContin] is equivalent to the [immediate-release oxycodone], with an adverse event profile that is as good as the [immediate-release oxycodone.] I would not allow a ‘better’ claim.” (emphasis in original);
- (iii) “The adverse experience profile of [OxyContin] is qualitatively similar to that of the parent drug, oxycodone;”
- (iv) “Withdrawal is possible in patients who have their dosage abruptly reduced or discontinued;”
- (v) “There is some evidence, both pharmacokinetic and clinical, that reduced acute opioid adverse effects may be expected in some patients, but there is not enough evidence to support an [adverse event] superiority claim [for OxyContin] against other marketed products.” (emphasis in original); and
- (vi) “Care should be taken to limit competitive promotion. [OxyContin] has been shown to be as good as current therapy, but has not been shown to have a significant advantage beyond reduction in frequency of dosing.”

21. Purdue later admitted the MORs were disclosed to certain of its supervisors and employees, although the MORs were not binding on Purdue.

22. Purdue’s NDA 20-553 was approved by the FDA on December 12, 1995, authorizing Purdue to market and sell a pharmaceutical product with the brand-name OxyContin in the United States. The FDA’s review of the application and proposed labeling concluded that “adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed draft labeling.”

23. Notwithstanding the statements in the Internal Medical Reviews (§ 20, *supra*), the Original OxyContin package insert that was approved by the FDA, among other things, stated

that “[d]elayed absorption, as provided by the OxyContin tables, is believed to reduce the abuse liability of a drug.”

Purdue’s marketing representations constituted a fraud on the health care providers and patients who relied on the Company’s false assurances

24. Purdue launched and grew the market for its new product with an aggressive and remarkably successful promotion strategy founded on omissions and false representations that minimized Original OxyContin’s potential for abuse and risk of substantial illicit distribution.

25. During OxyContin’s first five years in the marketplace, Purdue’s representations about Original OxyContin’s properties created an enormous market for the Drug as health care providers relying on Purdue’s assurances prescribed the Drug for legitimate patient pain management in a broad spectrum of chronic pain.

26. The Drug’s potency and its ease of procurement for non-medical use also made OxyContin the drug of choice to many addicts.

27. Original OxyContin sales generated approximately \$2.8 billion from January 1996 through June 30, 2001. By 2010, annual revenue from sales of the Drug reached approximately \$3 billion.

28. In June 2001, the falsity of Purdue’s representations was apparent in the public epidemic of addiction spawned by the Drug. The FDA and Purdue amended the Original OxyContin label to include cautionary language regarding the Drug’s potential for addiction and abuse, and Purdue abandoned its marketing misrepresentations.

29. Purdue’s false representations led to criminal misbranding charges against Purdue and two of its executives. In 2007 the defendants pled guilty to felony charges based on promotion and marketing, during the period from approximately January 1, 1996 to June 30,

2001, of Original OxyContin with the intent to defraud, in violation of the misbranding provisions of the federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* (*United States v. The Purdue Frederick Co., Inc.*, 495 F. Supp. 2d 569 (W.D. Va. 2007)).

30. The misbranding prosecution addressed OxyContin's label and Purdue's false and misleading marketing practices that perpetrated a fraud on prescribing health care providers and their patients. But it did not address the product itself.

The OxyContin pill matrix was designed and manufactured with a defect that rendered the Drug unreasonably dangerous and unsuitable for its intended purpose

31. OxyContin in its original formulation combined in a single tablet several doses of the potent opioid oxycodone intended to be released over a twelve-hour period. According to the FDA, "oxycodone is approximately twice as potent as oral morphine on a milligram basis." Purdue knew when it obtained FDA approval of Original OxyContin that the safety and efficacy of the Drug depended on its delayed absorption formulation, which it asserted would "reduce the abuse liability of the drug."

32. However, upon information and belief, during the pendency of NDA 20-553, neither the FDA nor Purdue

(i) evaluated the tablet that Purdue intended to use as a pill matrix for Original OxyContin to determine whether its physical or chemical hardness was sufficient to prevent inadvertent or deliberate tampering that would result in destruction of the time-release property and immediate release of the entire opioid dose, or

(ii) considered whether one or more clinical studies were required to determine on an ongoing basis whether OxyContin would cause addiction or withdrawal symptoms in persons who were prescribed extended or long-term dosages of Original OxyContin for use on an out-patient basis where ongoing unsupervised self-medication could be expected to occur.

This allegation is based on the absence of a record of any such evaluation or determination in documents concerning Purdue's NDA for Original OxyContin.

33. Purdue claimed in the patent application it filed in June 1995 for “Controlled Release Oxycodone Compositions,” that its proposed invention would provide a “controlled release composition” of its opioid medication “which acceptably controls pain over a substantially narrower daily dosage range” and “have substantially less inter-individual variation with regard to the dose of opioid analgesic required to control pain without unacceptable side effects.” U.S. Patent No. 5,508,042 (the “‘042 Patent”) was issued to Purdue on April 16, 1996.

34. Although Purdue’s ‘042 Patent identified several types of coatings it intended to use in order to create a controlled-release mechanism, it failed to identify any physical or chemical means by which to prevent nasal, oral, or injectable abuse of Original OxyContin’s active pharmaceutical ingredients.

35. In fact, Original OxyContin’s controlled-release mechanism, created by wet granulation and direct compression - - as opposed to other processes then known and used by others within the pharmaceutical industry - - was highly vulnerable to tampering and abuse because the tablet could be easily crushed to powder, destroying the time release property and releasing the full dose of oxycodone at once. Purdue later admitted that its “own study showed that a drug abuser could extract approximately 68% of the oxycodone from a single 10 mg OxyContin tablet by crushing the table, stirring it in water, and drawing the solution through cotton into a syringe.”

36. Although Purdue undertook certain in-house research and development of abuse deterrent technologies in the 1990s, its efforts did not focus on OxyContin or on abuse by snorting or injecting. Instead, it undertook to develop other abuse-deterrent technologies and thus knew or should have known of advances to the state of the art made by its competitors in the field of abuse-resistance controlled-release pharmaceutical products.

Purdue's prolonged search and protracted negotiations to obtain a method to produce crush resistant OxyContin

37. It was only after Purdue and the government publicly acknowledged the trend of OxyContin abuse in 2001 that the Company first ostensibly turned its attention to research and development that would address the design defect that made Original OxyContin particularly susceptible to abuse, namely that the timed-release properties were easily compromised by pulverizing the tablets, enabling abusers to either snort, ingest, or dissolve and inject the powder in order to experience the opioid high resulting from immediate delivery of the full dose of oxycodone into the bloodstream of the user.

38. Purdue's efforts proved unsuccessful notwithstanding the fact that the technology to address the design defect had been developed and disclosed as discussed in paragraphs 46-54, *infra*.

39. In 2003 Purdue investigated technology developed by the German pharmaceutical company Grunenthal GmbH ("Grunenthal"). Grunenthal's tamper resistant tablet had sufficient strength to prevent crushing; furthermore, to prevent injection, the compound formed a gel when dissolved in liquid. The U.S. Patent Office granted Grunenthal's November 20, 2003 application by issuing Patent No. 8,114,383 on February 14, 2012 with an expiration date of October 24, 2024 (the '383 Patent).

40. After years of negotiation, Purdue acquired a license to use Grunenthal's technology in a reformulated version of Original OxyContin (the "Reformulated OxyContin"), and sought FDA approval in 2007.

41. The FDA approved Purdue's application for Reformulated OxyContin in April 2010.

42. Purdue informed the FDA that it ceased distribution of Original OxyContin on August 10, 2010, and the FDA moved the Drug to its Discontinued Products List.

43. Upon information and belief, after Purdue terminated further shipments of Original OxyContin to its domestic customers in August 2010, it did not recall, buy back, or otherwise prevent distribution of the Drug that had already entered the stream of commerce. This allegation is based on the absence of any public recall or any reporting of any such recall, buy back or other steps to prevent further use of Original OxyContin; certain facts supporting this allegation are exclusively in Purdue's possession.

44. Purdue began distributing Reformulated OxyContin in August 2010, with FDA approval for the reformulated product accompanied by the same cautionary language regarding risks of addiction, withdrawal symptoms and development of tolerance that was approved in 2001.

45. It was not until April 16, 2013 -- the day that Purdue's '042 Patent expired -- that the FDA withdrew approval of Original OxyContin, stopped accepting applications for generic versions of that product, and approved a new label authorizing Purdue to market the abuse deterrent properties of Reformulated OxyContin.

For more than a decade, Purdue manufactured and sold Original OxyContin with an inherently dangerous design defect when a safer alternative was scientifically and economically feasible and practical for the Drug's intended use

46. It is now settled that the technology to create a tamper resistant oxycodone hydrochloride tablet was known and disclosed to the pharmaceutical industry on/or shortly after Original OxyContin hit the market.

47. On February 1, 2016 the United States Court of Appeals for the Federal Circuit affirmed the determinations of the United States District Court for the Southern District of New

York, which concluded that each and every claim asserted in Grunenthal's Patent '383, licensed by Purdue to formulate crush-resistant Reformulated OxyContin, was anticipated by prior art as early as 1997 or before. (*In re OxyContin Antitrust Litigation*, 994 F. Supp. 2d 367 (S.D.N.Y. 2014), *aff'd sub nom, In re Purdue Pharma L.P. v. Epic Pharma L.L.C.*, 811 F.3d 1345 (Fed. Cir. 2016)).

48. February 1, 2016, the date of the Federal Circuit's affirmance in *Purdue Pharma L.P. v. Epic L.L.C.*, is the date on which government officials could have known, knew, or should have known facts material to this action, specifically that all times relevant to this action, Original OxyContin suffered from a design defect, which from 1997, if not before, was remediable by state of the art technology.

49. That appeal arose from consolidated infringement actions that Purdue and Grunenthal brought in the Southern District of New York against four pharmaceutical manufacturers that sought FDA approval to sell generic versions of Reformulated OxyContin. . Following trial of the first action, the District Court ruled that the '383 patent was invalid and then dismissed the other three actions as collaterally estopped. (*In re Purdue Pharma*, 811 F.3d at 1348.)

50. The District Court based its determination that the '383 patent was invalid on an analysis of technology developed in 1995 by University of Texas scientists Dr. James McGinity and Dr. Feng Zhang who formulated a hot melt extrusion process for the manufacture of controlled-release tablets using high molecular weight polyethylene oxide ("PEO"), which as early as 1967 was known to strengthen tablets and make them crush resistant. (*In re OxyContin*, 994 F. Supp. 2d at 421-427). Zhang and McGinity and colleagues later reported that by 1995, more than 50 patents for hot melt extrusion formulations had been issued for pharmaceutical

systems. (Feng Zhang, James W. McGinity, *et al Pharmaceutical Applications of Hot-Melt Extrusion: Part I*, Drug Development and Industrial Pharmacy, 33:9, 909-926, DOI: 10.1080/03639040701498759 at 910 Figure 1 (2007)). This article was preceded by other related articles in the scientific literature that were available to, and routinely read by, researchers within the pharmaceutical industry.

51. McGinity's and Zhang's work was disclosed in an application to the World Intellectual Property Organization that was published on December 31, 1997. (*In re OxyContin*, 994 F. Supp. 2d at 421). In a 1999 application to United States Patent Office, the inventors claimed that their process was "particularly well-suited for oral delivery ... [of] controlled-release pharmaceutical formulations." U.S. Patent No. 6,488,963 entitled "Hot-Melt Extrudable Pharmaceutical Formulation" was issued in 2002 (the "'963 Patent"). Significantly, as the District Court found, "the McGinity Application discloses a dosage form comprising, among other ingredients, opioids." (*In re OxyContin*, 994 F. Supp. 2d at 422-423).

52. The District Court, discussing high molecular weight PEO's strength properties, noted that Zhang, while still a Ph.D. candidate, "applied basic principles of polymer chemistry and hot-melt extrusion to conclude, '[s]ince the polymeric carrier in its melt state during hot-melt extrusion is pressurized inside the extruder, the hot-melt extrudate is anticipated to possess a higher physical strength and lower porosity than tablets prepared by wet granulation and direct compression methods.'" (*Id.* at 426). And the decision remarks that "[i]f that reasoning would not have occurred naturally to one of ordinary skill in the art before Zhang committed it to paper in 1999, then it certainly became part of the art at that time." (*Id.*).

53. Yet Purdue used the wet granulation and direct compression process to manufacture Original OxyContin tablets that were highly susceptible to abuse for more than a decade thereafter.

54. The District Court concluded that “[Grunenthal’s] ’383 Patent recapitulated what the McGinity Application had already contributed to the art.” (*Id.* at 426). The Federal Circuit Agreed. (*In re Purdue Pharma*, 811 F.3d at 1359).

55. From approximately December 1995 to August 2010, Purdue manufactured and sold Original OxyContin with a known and remediable design defect that made the Drug unreasonably dangerous.

56. When manufactured and sold, each unit of Original OxyContin was defective because the pill matrix lacked sufficient physical or chemical harness to prevent inadvertent or deliberate tampering of the tablet with the result that the product was unsafe for its intended use - - “the management of moderate to severe pain in patients where use of an opioid analgesic is indicated for more than a few days.”

57. Original OxyContin was defective in design because actual and foreseeable harm, namely the addiction resulting from the Drug’s easily compromised controlled-release attribute, could have been reduced or avoided had Purdue adopted the safer alternative hot melt extrudable formulation that was known to, and within the state of the art of the pharmaceutical industry, in 1997 if not before. Purdue’s failure to incorporate the technology developed by Drs. McGinity and Zhang or others rendered Original OxyContin unsafe.

58. The country-wide “epidemic of abuse” attributable in significant part to Original OxyContin is well-documented and proves that the Drug was not safe for its intended use.

59. As a result of Purdue’s conduct the Plaintiff Governments have suffered two

categories of actual economic injury: (i) the sums paid to reimburse prescription claims for Original OxyContin that was sold with an inherently dangerous and remediable design defect; and (ii) the billions of dollars expended to pay for programs to protect the public's health and safety that relate to the immediate consequences of substance addiction and ongoing prevention and treatment programs (the "Impacted Programs").

60. For example, in 2009 the National Center on Addiction and Substance Abuse ("CASA") reported that in 2005 the State of New York spent 21.1% of its General Fund (\$13.132 billion) on its Impacted Programs, an amount that translates to \$680.19 per capita. The report also stated that in 2005 the states of California, New York, Texas, Florida, Pennsylvania, Ohio, Michigan, Illinois, Massachusetts and North Carolina expended a combined \$73.3 billion on their Impacted Programs.

61. CASA reported that the fiscal impact of substance abuse – including prescription drug abuse and addiction – on federal, state and local budgets in 2005 was at least \$467.7 billion for all public programs, representing 10.7 % of the collective \$4.4 trillion in those budgets.

62. The actual economic injury suffered by the Plaintiff Governments is staggering.

63. The Plaintiff Governments expended billions of dollars to reimburse claims for Purdue's defective OxyContin and billions more on Impacted Programs.

Purdue caused, and knowingly and tacitly colluded with certain doctors, clinics, pharmacies, and other health care services and products providers to cause false claims for government reimbursement to be submitted in the absence of a bona-fide certification of medical necessity

64. Patients with legitimate medical need were victimized when they and their doctors relied on Purdue's false assurances regarding the risks associated with the use of Original OxyContin. The 2001 amendments to the OxyContin label enabled patients with legitimate

medical need and their health care providers to make treatment decisions based on accurately informed risk/benefit analyses and diminish the potential for inadvertent addiction.

65. But those warnings did nothing to quell the overwhelming demand for the Drug by the enormous country-wide illicit market and the so-called “pill mills” that proliferated to feed the insatiable demand for non-medical use of Original OxyContin. That market existed specifically because of the design defect that made Original OxyContin as formulated easy to crush, facilitating abuse.

66. Certain doctors, clinics, pharmacies and other health services providers prescribed and dispensed Original OxyContin *because* of the attributes that made it prone to tampering and abuse and not for any of the Drug’s other attributes (hereinafter “Illicit Providers”). Their customers were abusers who procured Original OxyContin for their own consumption and/or resale on the black market.

67. The Illicit Providers prescribed or provided Original OxyContin for non-medical reasons and then submitted fraudulent claims for reimbursement by the Plaintiff Governments that falsely certified that the claims were based on a determination of medical necessity.

68. Before and after 2001, Purdue supplied Original OxyContin to Illicit Providers in amounts that would lead any reasonable pharmaceutical firm to conclude were not legitimately based on medical necessity.

69. Federal law and regulations, applicable to participating states, require assurance that claims for Medicaid and Medicare reimbursement of services rendered or items provided to beneficiaries and recipients are (1) provided only when medically necessary, (2) of a quality that meets professionally recognized health care standards, and (3) supported by evidence of medical necessity and quality. 42 U.S.C. § 1320c-5, 42 C.F.R. § 1004.10, and applicable laws, rules and

regulations of the respective Plaintiff States. The Illicit Providers' claims for Original OxyContin reimbursement falsely assured the Plaintiff Governments with respect to all three of the foregoing factors. Those claims were not based on medical necessity, did not conform to professionally recognized health care standards, and were not supported by evidence of medical necessity and quality.

70. By supplying the Illicit Providers that Purdue knew or should have known dispensed Original OxyContin for non-medical use, Purdue knowingly colluded with them in a tacit conspiracy that resulted in the submission of claims for reimbursement from the Plaintiff Governments that falsely certified medical necessity, rendering each of those claims false.

71. Beginning at the latest in 2002, the year in which Purdue later revealed that it maintained a database of health care providers whose profiles indicated they were recklessly prescribing Original OxyContin to addicts and drug dealers, Purdue was able to identify the persons and entities that were diverting the Drug for non-medical use.

72. After 2001, if not before, Purdue became aware of the growing illicit market for Original OxyContin and knew that an increasingly sizable percentage of its overall market share resulted from the illicit distribution and sale of the Drug. Plaintiffs assert, upon information and belief based on facts exclusively within Purdue's possession, that a statistical sampling of Purdue's proprietary sales and distribution data will demonstrate the full extent of the illicit diversion that occurred, as well as the date when Purdue knew and had reason to know that it was tacitly participating in a fraudulent scheme related to the Illicit Providers' false certifications of medical necessity for purpose of government reimbursement.

73. Diligent use of that information by Purdue would have resulted in a significantly less profitable venture for the Company.

74. There is abundant evidence of the alleged fraudulent scheme in the many hundreds of prosecutions, convictions, and medical license suspensions throughout the country. For example, Masoud Bamdad, a doctor who practiced in San Fernando, California was prosecuted and convicted based on evidence that he received approximately \$1.5 million/year in or about 2007-2008 from prescribing OxyContin, among other pain medications, without a legitimate medical purpose. Similarly, Eleanor Santiago and at least 15 other doctors who were part of the Lake Medical Group in Los Angeles were convicted of knowingly diverting approximately 1 million doses of OxyContin by prescribing the Drug to people who had no medical need and submitting claims for government reimbursement for those unneeded prescriptions beginning in 2008. Myriad such stories across the country clearly evidence the fraudulent scheme.

75. Telling evidence supporting an inference of the fraudulent scheme alleged herein comes from Purdue's own study of certain suspect prescribers, which revealed that after the Company replaced the original formulation of OxyContin with the crush-resistant reformulated version in August 2010, prescriptions for maximum strength OxyContin, the dosage of choice for most addicts, decreased by 80%.

76. Purdue supplied OxyContin with a known and remediable design defect to Illicit Providers that the Company knew or should have known were not treating people with legitimate medical need, thereby facilitating and perpetuating the black market for OxyContin.

77. In so doing, Purdue caused - - and knowingly and tacitly conspired with Illicit Providers to cause - - submission of claims for government reimbursement that falsely certified medical necessity.

78. Purdue and the Illicit Providers knowingly and tacitly agreed to the submission of

false records or statements, namely certification of medical necessity that were not in fact based on medical need, for the purpose of inducing the Plaintiff Governments to pay the falsely certified claims.

79. It was not only foreseeable to Purdue that the Illicit Providers were submitting claims that were ineligible for government reimbursement because they were prescribed without any finding of medical need, but it was also the intended consequence, which was knowingly and tacitly pursued by Purdue.

80. Purdue and the Illicit Providers knew and tacitly agreed that false certification of medical necessity would have a material effect on the Government Plaintiffs' decisions to pay the false claims because the Plaintiff Governments were required by law to refuse claims that were not based on certified medical need.

81. One or more of the following federal government payors sustained actual damages when they reimbursed fraudulently certified claims for Original OxyContin: the Medicare Program (Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll); the Medicaid Program (Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v); the Tricare Program (f/k/a the Civilian Health and Medical Program of the Uniformed Services, 10 U.S.C. §§ 1071-1110), administered by the Department of Defense Tricare Management Activity; the Federal Employees Health Benefits Program, administered by Office of Personnel Management; and Department of Labor programs under the Federal Employees' Compensation Act (5 U.S.C. § 8101*et seq.*), the Energy Employees Occupational Illness Compensation Program Act (42 U.S.C. § 7348 *et seq.*), and the Black Lung Benefits Act, (30 U.S.C. § 901*et seq.*) administered by the Department of Labor's Office of Workers' Compensation Programs.

82. Each Plaintiff State, through the cost-sharing provisions of Medicaid, sustained

actual damages for falsely certified Original OxyContin claims that are measured by the portion of those claims that the federal government does not reimburse.

83. Purdue's misconduct perpetrated a fraud on the Plaintiff Governments.

The claims asserted herein are not barred by prior pleas or settlement agreements

84. In 2007, The Purdue Frederick Company entered a plea agreement in *United States of America v. The Purdue Frederick Company*, which was accepted by the District Court in a decision published at 492 F. Supp. 2d 569 (W.D. Va. 2007). Part of that plea agreement required restitution payments to be made to the federal government in settlement of its civil claims and to state governments electing to settle their civil claims.

85. The settlement agreement between the United States of America on the one hand, and The Frederick Purdue Company and Purdue Pharma L.P., on the other hand (the "Federal Settlement Agreement"), provided that its provisions settled civil claims against those Purdue entities as follows:

during the time period from 1996 through 2005, engaging in the following conduct with respect to the marketing of OxyContin (hereinafter referred to as the "Covered Conduct"): The United States alleges that Purdue misbranded the drug OxyContin with the intent to defraud or mislead in violation of 21 U.S.C. § 333(a)(2). Specifically, the Government alleges that Purdue marketed OxyContin as less subject to abuse, illicit use and diversion and as less addictive and less likely to cause tolerance and withdrawal than other pain medications and that Purdue knew that these marketing claims were false and misleading, causing damages to Federal government payors.

86. Federal Settlement Agreement also provided that

Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or persons (including Purdue [Pharma, L.P. and The Frederick Purdue Company]) are the following :

- a. Any civil criminal, or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);

- b. Any criminal liability;
- c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs;
- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability based upon such obligations as are created by this Agreement;
- f. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- g. Any liability or claims for personal injury or property damage or for other consequential damages arising from the Covered Conduct; and
- h. Any liability for failure to deliver goods or services due.

87. The Federal Settlement Agreement does not limit or preclude any of the claims for recovery in this Complaint.

88. The Plaintiff States entered agreements settling their respective civil claims against Purdue on the same or similar terms and conditions as those set forth in the Federal Settlement Agreement with regard to the conduct covered and the express reservations and exceptions.

89. The Plaintiff States' respective settlement agreements with Purdue entities do not limit or preclude any of the claims for recovery in this Complaint.

FIRST CAUSE OF ACTION
Federal False Claims Act
(31 U.S.C. § 3729 *et seq.*).

90. Relator repeats and realleges the foregoing allegations and incorporates them by reference as if fully set forth herein.

91. Even after 2001, when the public epidemic of addiction in large part attributable to the Original OxyContin design defect described above came to light, through August 10,

2010, Purdue continued to supply Original OxyContin to certain doctors, clinics, pharmacies and other health care services providers with frequency and in amounts that would lead any reasonable pharmaceutical company to conclude that the drug was being dispensed for non-medical use. In so doing, Purdue caused, and knowingly and tacitly conspired to cause, the submission of claims for reimbursement for Original OxyContin by those illicit doctors, clinics, pharmacies, and other health care providers that were not based on the legitimate determination of medical necessity as required by Medicaid and Medicare laws and regulations, among others, thus rendering the claims false.

92. Purdue knowingly has caused to be presented false or fraudulent claims for payment by the United States in violation of 31 U.S.C. § 3729(a)(1)(A), and prior to amendment in May 2009, 31 U.S.C. § 3729(a)(1).

93. Purdue knowingly has caused to be made or used false records or statements to induce the United States to pay or approve false or fraudulent claims in violation of 31 U.S.C. § 3729(a)(1)(B), and prior to amendment in May 2009, 31 U.S.C. § 3729(a)(2).

94. Purdue knowingly and tacitly conspired with certain doctors, clinics, pharmacies and other providers of health care and products to defraud the United States by causing to be presented false or fraudulent claims for payment by the United States and by causing to be made or used false records or statements to induce the United States to pay or approve false or fraudulent claims in violation of 31 U.S.C. § 3729(a)(1)(C), and prior to amendment in May 2009, 31 U.S.C. 3729(a)(3).

95. Purdue knew, acted in deliberate ignorance of, or recklessly disregarded the fact that the Illicit Providers were (i) presenting false claims for payment by the United States and/or (ii) making or using false records or statements to induce the United States to pay or approve

false claims.

96. As a consequence of Purdue's conduct, the United States has suffered actual damages amounting to billions of dollars in with the amount to be determined at trial.

SECOND CAUSE OF ACTION

**California False Claims Act
(Cal. Gov. Code § 12650 *et seq.*)**

97. Relator repeats and realleges the foregoing allegations and incorporates them by reference as if fully set forth herein.

98. Based on the foregoing allegations, Purdue is liable under California False Claims Act (Cal. Gov. Code § 12650 *et seq.*).

99. As a consequence of Purdue's conduct, California has suffered actual damages with the amount to be determined at trial.

THIRD CAUSE OF ACTION

**Colorado Medicaid False Claims Act
(Colo. Rev. Stat. § 25.5-4-303.5, *et seq.*)**

100. Relator repeats and realleges the foregoing allegations and incorporates them by reference as if fully set forth herein.

101. Based on the foregoing allegations, Purdue is liable under Colorado Medicaid False Claims Act (Colo. Rev. Stat. § 25.5-4-303.5, *et seq.*).

102. As a consequence of Purdue's conduct Colorado has suffered actual damages in an amount to be determined at trial.

FOURTH CAUSE OF ACTION

**Connecticut False Claims Act
(Conn. Gen. Stat. §§ 17b-301a *et seq.*)
(amended and re-codified as Conn. Gen. Stat. § 4-274 *et seq.*)**

103. Relator repeats and realleges the foregoing allegations and incorporates them by

reference as if fully set forth herein.

104. Based on the foregoing allegations, Purdue is liable under the Connecticut False Claims Act (Conn. Gen. Stat. § 4-274 *et seq.*).

105. As a consequence of Purdue's conduct, Connecticut has suffered actual damages with the amount to be determined at trial.

FIFTH CAUSE OF ACTION
Delaware False Claims and Reporting Act
(Del. Code Ann. tit. 6 § 1201 *et seq.*)

106. Relator repeats and realleges the foregoing allegations and incorporates them by reference as if fully set forth herein.

107. Based on the foregoing allegations, Purdue is liable under the Delaware False Claims and Reporting Act (Del. Code Ann. tit. 6 § 1201 *et seq.*).

108. As a consequence of Purdue's conduct Delaware has suffered actual damages in an amount to be determined at trial.

SIXTH CAUSE OF ACTION
Florida False Claims Act
(Fla. Stat. Ann. § 68.081 *et seq.*)

109. Relator repeats and realleges the foregoing allegations and incorporates them by reference as if fully set forth herein.

110. Based on the foregoing allegations, Purdue is liable under the Florida False Claims Act (Fla. Stat. Ann. § 68.081 *et seq.*).

111. As a result of Purdue's conduct, Florida has suffered damages in an amount to be determined at trial.

SEVENTH CAUSE OF ACTION

**Georgia State False Medicaid Claims Act
(Ga. Code Ann. § 49-4-168)**

**Georgia Taxpayers Protection and False Claims Act
(Ga. Code Ann. § 23 - 3 – 120 *et seq.*)**

112. Relator repeats and realleges the foregoing allegations and incorporates them by reference as if fully set forth herein.

113. Based on the foregoing allegations, Purdue is liable under the Georgia State False Medicaid Claims Act (Ga. Code Ann. § 49-4-168) and/or under the Georgia Taxpayers Protection and False Claims Act (Ga. Code Ann. § 23 - 3 – 120 *et seq.*).

114. As a result of Purdue's conduct, Georgia has suffered damages in an amount to be determined at trial.

EIGHTH CAUSE OF ACTION

**Hawaii False Claims Act
(Haw. Rev. Stat. § 661-21 *et seq.*)**

115. Relator repeats and realleges the foregoing allegations and incorporates them by reference as if fully set forth herein.

116. Based on the foregoing allegations, Purdue is liable under the Hawaii False Claims Act (Haw. Rev. Stat. § 661-21 *et seq.*).

117. As a result of Purdue's damages Hawaii has suffered damages in an amount to be determined at trial.

NINTH CAUSE OF ACTION

**Illinois False Claim Act
(f/k/a Illinois Whistleblower Reward and Protection Act)
(740 Ill. Comp. Stat. Ann. § 175/1 *et seq.*)**

118. Relator repeats and realleges the foregoing allegations and incorporates them by reference as if fully set forth herein.

119. Based on the foregoing allegations, Purdue is liable under the Illinois Whistleblower Reward and Protection Act (740 Ill. Comp. Stat. Ann. § 175/1 *et seq.*).

120. As a result of Purdue's damages Illinois has suffered damages in an amount to be determined at trial.

TENTH CAUSE OF ACTION
Indiana False Claims and Whistleblower Protection Act
(Ind. Code Ann. § 5-11-5.5 *et seq.*)

121. Relator repeats and realleges the foregoing allegations and incorporates them by reference as if fully set forth herein.

122. Based on the foregoing allegations, Purdue is liable under Indiana False Claims and Whistleblower Protection Act (Ind. Code Ann. § 5-11-5.5 *et seq.*).

123. As a result of Purdue's damages Indiana has suffered damages in an amount to be determined at trial.

ELEVENTH CAUSE OF ACTION
Iowa False Claims Act
(Iowa Code Ann. § 685.1 *et seq.*)

124. Relator repeats and realleges the foregoing allegations and incorporates them by reference as if fully set forth herein.

125. Based on the foregoing allegations, Purdue is liable under Iowa False Claims Act (Iowa Code Ann. § 685.1 *et seq.*).

126. As a result of Purdue's conduct Iowa has suffered damages in an amount to be determined at trial.

TWELFTH CAUSE OF ACTION
Louisiana Medical Assistance Programs Integrity Law
(La. Stat. Ann. § 46:437.1 *et seq.*)

127. Relator repeats and realleges the foregoing allegations and incorporates them by

reference as if fully set forth herein.

128. Based on the foregoing allegations, Purdue is liable under Louisiana Medical Assistance Programs Integrity Law (La.. Stat. Ann. § 46:437.1 *et seq.*).

129. As a result of Purdue's conduct Louisiana has suffered damages in an amount to be determined at trial.

THIRTEENTH CAUSE OF ACTION
Maryland Health Program Integrity and Recovery Act
(Md. Code Ann. Health- Gen. § 2-501 *et seq.*)

130. Relator repeats and realleges the foregoing allegations and incorporates them by reference as if fully set forth herein.

131. Based on the foregoing allegations, Purdue is liable under Maryland Health Program Integrity and Recovery Act (Md. Code Ann. Health- Gen. § 2-501 *et seq.*)

132. As a result of Purdue's conduct Maryland has suffered damages in an amount to be determined at trial.

FOURTEENTH CAUSE OF ACTION
Massachusetts False Claims Act
(Mass. Gen. Laws Ann. ch. 12 § 5A *et seq.*)

133. Relator repeats and realleges the foregoing allegations and incorporates them by reference as if fully set forth herein.

134. Based on the foregoing allegations, Purdue is liable under Massachusetts False Claims Act (Mass. Gen. Laws Ann. ch. 12 § 5A *et seq.*).

135. As a result of Purdue's conduct Massachusetts has suffered damages in amount to be determined at trial.

FIFTEENTH CAUSE OF ACTION
Michigan Medicaid False Claims Act
(Mich. Comp. Laws Ann. § 400.601 *et seq.*)

136. Relator repeats and realleges the foregoing allegations and incorporates them by reference as if fully set forth herein.

137. Based on the foregoing allegations, Purdue is liable under Michigan Medicaid False Claims Act (Mich. Comp. Laws Ann. § 400.601 *et seq.*).

138. As a result of Purdue's conduct Michigan has suffered damages in an amount to be determined at trial.

SIXTEENTH CAUSE OF ACTION
Minnesota False Claims Act
(Minn. Stat. Ann. § 15C.01 *et seq.*)

139. Relator repeats and realleges the foregoing allegations and incorporates them by reference as if fully set forth herein.

140. Based on the foregoing allegations, Purdue is liable under Minnesota False Claims Act (Minn. Stat. Ann. § 15C.01 *et seq.*).

141. As a result of Purdue's conduct Minnesota has suffered damages in an amount to be determined at trial.

SEVENTEENTH CAUSE OF ACTION
Montana False Claims Act
(Mont. Code Ann. § 17-8-401 *et seq.*)

142. Relator repeats and realleges the foregoing allegations and incorporates them by reference as if fully set forth herein.

143. Based on the foregoing allegations, Purdue is liable under Montana False Claims Act (Mont. Code Ann. § 17-8-401 *et seq.*).

144. As a result of Purdue's conduct Montana has suffered damages in an amount to be

determined at trial.

EIGHTEENTH CAUSE OF ACTION

**Nevada False Claims Act
(Nev. Rev. Stat. Ann. § 357.010 *et seq.*)**

145. Relator repeats and realleges the foregoing allegations and incorporates them by reference as if fully set forth herein.

146. Based on the foregoing allegations, Purdue is liable under Nevada False Claims Act (Nev. Rev. Stat. Ann. § 357.010 *et seq.*).

147. As a result of Purdue's conduct Nevada has suffered damages in an amount to be determined at trial.

NINETEENTH CAUSE OF ACTION

**New Jersey False Claims Act
(N.J. Stat. Ann. § 2A:32C-1 *et seq.*)**

148. Relator repeats and realleges the foregoing allegations and incorporates them by reference as if fully set forth herein.

149. Based on the foregoing allegations, Purdue is liable under New Jersey False Claims Act (N.J. Stat. Ann. § 2A:32C-1 *et seq.*).

150. As a result of Purdue's conduct New Jersey has suffered damages in an amount to be determined at trial.

TWENTIETH CAUSE OF ACTION

**New Mexico Medicaid False Claims Act
(N.M. Stat. Ann. 27-14-1 *et seq.*)**

151. Relator repeats and realleges the foregoing allegations and incorporates them by reference as if fully set forth herein.

152. Based on the foregoing allegations, Purdue is liable under New Mexico Medicaid False Claims Act (N.M. Stat. Ann. 27-14-1 *et seq.*).

153. As a result of Purdue's conduct New Mexico has suffered damages in an amount to be determined at trial.

TWENTY-FIRST CAUSE OF ACTION
New York False Claims Act
(N.Y. Fin. Law § 187 *et seq.*)

154. Relator repeats and realleges the foregoing allegations and incorporates them by reference as if fully set forth herein.

155. Based on the foregoing allegations, Purdue is liable under New York False Claims Act (N.Y. Fin. Law § 187 *et seq.*).

156. As a result of Purdue's conduct New York has suffered damages in an amount to be determined at trial.

TWENTY-SECOND CAUSE OF ACTION
North Carolina State False Claims Act
(N.C. Gen. Stat. Ann. § 1-605 *et seq.*)

157. Relator repeats and realleges the foregoing allegations and incorporates them by reference as if fully set forth herein.

158. Based on the foregoing allegations, Purdue is liable under North Carolina State False Claims Act (N.C. Gen. Stat. Ann. § 1-605 *et seq.*).

159. As a result of Purdue's conduct North Carolina has suffered damages in an amount to be determined at trial.

TWENTY-THIRD CAUSE OF ACTION
Oklahoma Medicaid False Claims Act
(Okla. Stat. Ann. Tit. 63 § 5053 *et seq.*)

160. Relator repeats and realleges the foregoing allegations and incorporates them by reference as if fully set forth herein.

161. Based on the foregoing allegations, Purdue is liable under Oklahoma Medicaid

False Claims Act (Okla. Stat. Ann. Tit. 63 § 5053 *et seq.*).

162. As a result of Purdue's conduct Oklahoma has suffered damages in an amount to be determined at trial.

TWENTY-FOURTH CAUSE OF ACTION
Rhode Island State False Claims Act
(R.I. Gen. Laws Ann. § 9-1.1-1 *et seq.*)

163. Relator repeats and realleges the foregoing allegations and incorporates them by reference as if fully set forth herein.

164. Based on the foregoing allegations, Purdue is liable under Rhode Island State False Claims Act (R.I. Gen. Laws Ann. § 9-1.1-1 *et seq.*).

165. As a result of Purdue's conduct Rhode Island has suffered damages in an amount to be determined at trial.

TWENTY-FIFTH CAUSE OF ACTION
Tennessee False Claims Act and Medicaid False Claims Act
(Tenn. Code Ann. § 4-18-101 *et seq.* and 71-5-181 *et seq.*)

166. Relator repeats and realleges the foregoing allegations and incorporates them by reference as if fully set forth herein.

167. Based on the foregoing allegations, Purdue is liable under Tennessee False Claims Act and Medicaid False Claims Act (Tenn. Code Ann. section 4-18-101 *et seq.* and 71-5-181 *et seq.*).

168. As a result of Purdue's conduct Tennessee has suffered damages in an amount to be determined at trial.

TWENTY-SIXTH CAUSE OF ACTION
Texas Medicaid False Claims Fraud Prevention Law
(Tex. Hum. Res. Code Ann. § 36.001 *et seq.*)

169. Relator repeats and realleges the foregoing allegations and incorporates them by

reference as if fully set forth herein.

170. Based on the foregoing allegations, Purdue is liable under Texas Medicaid False Claims Fraud Prevention Law (Tex. Hum. Res. Code Ann. § 36.001 *et seq.*).

171. As a result of Purdue's conduct Texas has suffered damages in an amount to be determined at trial.

TWENTY-SEVENTH CAUSE OF ACTION

**Vermont False Claims Act
(Vt. Stat. Ann. tit. 32 § 630 *et seq.*)**

172. Relator repeats and realleges the foregoing allegations and incorporates them by reference as if fully set forth herein.

173. Based on the foregoing allegations, Purdue is liable under Vermont False Claims Act (Vt. Stat. Ann. Tit. 32 § 630 *et seq.*).

174. As a result of Purdue's conduct Vermont has suffered damages in an amount to be determined at trial.

TWENTY-EIGHTH CAUSE OF ACTION

**Virginia Fraud Against Taxpayers Act
(Va. Code Ann. § 8.01-216.1 *et seq.*)**

175. Relator repeats and realleges the foregoing allegations and incorporates them by reference as if fully set forth herein.

176. Based on the foregoing allegations, Purdue is liable under Virginia Fraud Against Taxpayers Act (Va. Code Ann. § 8.01-216.1 *et seq.*).

177. As a result of Purdue's conduct Virginia has suffered damages in an amount to be determined at trial.

TWENTY-NINTH CAUSE OF ACTION
Washington State Medicaid Fraud False Claims Act
(Wash. Rev. Code Ann. § 74:66.005 *et seq.*)

178. Relator repeats and realleges the foregoing allegations and incorporates them by reference as if fully set forth herein.

179. Based on the foregoing allegations, Purdue is liable under Washington State Medicaid Fraud False Claims Act (Wash. Rev. Code Ann. § 74:66.005 *et seq.*).

180. As a result of Purdue's conduct Washington has suffered damages in an amount to be determined at trial.

THIRTIETH CAUSE OF ACTION
District of Columbia False Claims Act (a/k/a Procurement Related Claims Act)
(D.C. Code Ann. § 2-381.01 *et seq.*)

181. Relator repeats and realleges the foregoing allegations and incorporates them by reference as if fully set forth herein.

182. Based on the foregoing allegations, Purdue is liable under District of Columbia False Claims Act (D.C. Code Ann. § 2-381.01 *et seq.*).

183. As a result of Purdue's conduct the District of Columbia has suffered damages in an amount to be determined at trial.

THIRTY-FIRST CAUSE OF ACTION
Products Liability – Design Defect

184. Relator repeats and realleges the foregoing allegations and incorporates them by reference as if fully set forth herein.

185. Purdue manufactured and sold Original OxyContin from approximately January 1, 2006 to August 10, 2010.

186. An inherently and unreasonably dangerous design defect existed at the time

Purdue distributed Original OxyContin to doctors, clinics, pharmacies and other health care providers to be dispensed to patients for pain management, and because of that defect Original OxyContin was not reasonably suitable for its intended use -- the management of moderate to severe pain in patients where use of an opioid analgesic is indicated for more than a few days.

187. Original OxyContin was defective because actual and foreseeable harm, namely the risk of a large-scale addiction and concomitant illicit diversion resulting from the Drug's easily compromised controlled-release attribute, could have been reduced or avoided had Purdue adopted the safer alternative formulation that was known, disclosed, and within the state of the art by 1997 if not before, rendering Original OxyContin unsafe.

188. Rampant abuse resulted from the Original OxyContin design defect, which rendered every Original OxyContin Purdue manufactured and sold from December 1995 to August 2010 susceptible to facile tampering and abuse. Purdue facilitated and perpetuated the consequential black market that arose by knowingly and tacitly conspiring to supply the Drug to Illicit Providers whose costs were reimbursed the Plaintiff Governments.

189. Original OxyContin's unreasonably dangerous and defective design defect -- the ease with which it could be pulverized to immediately release an entire dose of its active pharmaceutical ingredient oxycodone that could be inhaled, injected, or ingested -- was the proximate cause of the Plaintiff Governments' respective actual economic injuries, specifically multiple billions of dollars Plaintiff Governments' expended (i) to reimburse claims for Original OxyContin prescriptions and (ii) to fund programs to protect the public's health and safety that relate to the immediate consequences of substance addiction and ongoing prevention and treatment programs.

190. As a result of Purdue's conduct, the Plaintiff Governments have suffered damages

in an amount to be determined at trial.

THIRTY-SECOND CAUSE OF ACTION
Unjust Enrichment

191. Relator repeats and realleges the foregoing allegations and incorporates them by reference as if fully set forth herein.

192. Purdue has been unjustly enriched by the gross revenues and profits it has received as a consequence of the sale of Original OxyContin, which generated more than \$25 billion for Purdue between 1996 and 2010.

193. During that period Purdue manufactured and sold within the United States millions of Original OxyContin prescriptions amounting to more than 45 tons of the Drug.

194. In 2001, Purdue made a decision to develop a tablet that would be difficult to crush or to syringe. The Company made that decision after it became aware that significant numbers of its health care provider customers were engaged in an illegal enterprise whereby they wrote prescription slips for illicit diversion to persons then addicted to Original OxyContin or to the persons who supplied them.

195. Although Purdue knew that Original OxyContin suffered from an inherently and unreasonably dangerous defect that rendered the Drug's release-control attributes susceptible to easy destruction, the Company failed to incorporate technology, which was known by and disclosed to researchers within the pharmaceutical industry by 1997, to produce a tablet with tamper and crush resistant attributes until 2010 when the Company commenced distribution of Reformulated OxyContin. That failure is contrary to the standards of reasonable care then practiced within the domestic and international pharmaceutical industry.

196. To permit Purdue to retain profits that it unjustly realized as a consequence of

Original OxyContin sales offends fundamental principles of justice, equity and good conscience.

197. Restitution requires that Purdue as a conscious wrongdoer must fully disgorge its unjustly realized profits.

198. The Plaintiff Governments are entitled to receive Purdue's unjustly realized profits in an amount to be determined at trial.

PRAYER FOR RELIEF

Based on the foregoing, Relator, on behalf of the Plaintiff Governments, respectfully requests that the Court enter an order

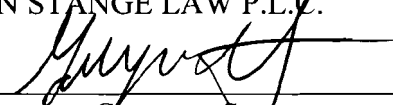
- (i) granting judgment in favor of Plaintiffs;
- (ii) awarding all available damages to Plaintiff Governments for Defendants' violations of the federal and state false claims acts pleaded herein;
- (iii) awarding Plaintiff Governments damages for the economic injuries sustained as a result of Defendants' manufacture and sale of Original OxyContin with an inherently and unreasonably dangerous, remediable design defect;
- (iv) directing Defendants to disgorge and deliver to Government Plaintiffs profits unjustly realized from the sale of Original OxyContin;
- (v) awarding Relator all costs of this action, including attorneys fees and expenses and costs, pursuant to the federal and state false claims acts cited above;
- (vi) awarding Relator the allowable relator share pursuant to 31 U.S.C. § 3730(a) and comparable provisions of the states' false claims acts; and
- (vii) granting any further or different relief as the Court deems just and proper.

PLAINTIFFS HEREBY DEMAND TRIAL BY JURY ON ALL CLAIMS RAISED IN THIS ACTION THAT ARE TRIABLE BY A JURY.

Dated: Shelburne, Vermont
May 16, 2016

VON STANGE LAW P.L.C.

By



Gary von Stange

*(Complaint for filing is accompanied by
Motion for Pro Hac Vice Admission, pursuant
to Local Rule 85.5.3)*

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